

107TH CONGRESS  
1ST SESSION

# S. 1752

To amend the Public Health Service Act with respect to facilitating the development of microbicides for preventing transmission of HIV and other sexually transmitted diseases.

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## IN THE SENATE OF THE UNITED STATES

NOVEMBER 30, 2001

Mr. CORZINE (for himself, Ms. SNOWE, Ms. CANTWELL, Mr. DODD, Mr. LEAHY, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Public Health Service Act with respect to facilitating the development of microbicides for preventing transmission of HIV and other sexually transmitted diseases.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

### 3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Microbicide Develop-  
5 ment Act of 2001”.

### 6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1           (1) Sexually transmitted diseases (“STDs”)  
2           and the human immunodeficiency virus (“HIV”) are  
3           producing serious and costly epidemics of infectious  
4           disease in populations worldwide.

5           (2) This year, 15,400,000 people in the United  
6           States will acquire a new STD.

7           (3) Globally, 36,100,000 people are infected  
8           with HIV, with more than 15,000 new infections oc-  
9           curring daily.

10          (4) Racial and ethnic minorities have been dis-  
11          proportionately infected with STDs, especially HIV.  
12          For example, although together African American  
13          and Latina women represent roughly 25 percent of  
14          the total U.S. female population, they account for 77  
15          percent of all reported female HIV cases.

16          (5) STDs cause serious, costly, even deadly con-  
17          ditions for women and their children: infertility,  
18          pregnancy complications, cervical cancer, infant mor-  
19          tality, and higher risk of contracting HIV.

20          (6) Estimated annual costs of STDs and their  
21          complications in the United States range from  
22          \$8,400,000,000 in direct medical costs to nearly  
23          \$20,000,000,000, including out-of-pocket costs and  
24          lost productivity.

1           (7) Microbicides are a promising new tech-  
2 nology for STD and HIV prevention.

3           (8) Microbicides are user-controlled products  
4 that could kill, block, or inactivate the bacteria and  
5 viruses that cause STDs and HIV.

6           (9) Microbicides would fill a critical gap in the  
7 array of STD-prevention technologies, first as an  
8 important backup or alternative to the condom, and  
9 second, as a technology that, unlike most vaccines,  
10 could offer protection against various STDs, not just  
11 HIV.

12           (10) Several potential microbicides are poised  
13 for successful development; more than 20 products  
14 are in clinical trials and nearly 35 promising com-  
15 pounds exist that could be investigated further.

16           (11) Studies into the market potential for  
17 microbicides indicate that they would have broad ap-  
18 peal. One nationally representative survey indicated  
19 that at least 21,000,000 sexually active women in  
20 the United States would be interested in such prod-  
21 ucts, if they were available.

22           (12) Federal support for microbicide research  
23 and development is crucial.

24           (13) At present, there is insufficient economic  
25 incentive for large pharmaceutical companies to be-

1       come actively engaged in microbicide research and  
2       development.

3           (14) Numerous small biotechnology companies  
4       and university researchers are actively engaged in  
5       microbicide research, but they are almost totally de-  
6       pendent on public-sector grants to continue their  
7       work and test their products.

8           (15) Despite public health need and tremendous  
9       scientific opportunity, microbicide research and de-  
10      velopment currently receives less than 1 percent of  
11      the Federal HIV research budget—not nearly  
12      enough to keep pace with the raging STD and HIV  
13      epidemics.

14          (16) Existing public sector grants for  
15      microbicides are too small and too short-term to  
16      move product leads forward, and the availability of  
17      clinical trial sites is limited by funding constraints.

18          (17) There is a backlog in the research and de-  
19      velopment pipeline, so that innovative and promising  
20      product concepts are languishing, while infection  
21      rates are growing.

22          (18) For significant progress to be made, the  
23      current amount of Federal investment needs to in-  
24      crease to \$75,000,000 in fiscal year 2002, to  
25      \$100,000,000 in fiscal year 2003, with

1       \$100,000,000 yearly in the successive out-years as  
 2       required, in order to sustain multiyear funding at  
 3       a productive level.

4       **TITLE       I—MICROBICIDE       RE-**  
 5       **SEARCH AT THE NATIONAL**  
 6       **INSTITUTES OF HEALTH**

7       **SEC. 101. OFFICE OF AIDS RESEARCH; PROGRAM REGARD-**  
 8               **ING MICROBICIDES FOR PREVENTING TRANS-**  
 9               **MISSION OF HIV AND OTHER SEXUALLY**  
 10              **TRANSMITTED DISEASES.**

11       Subpart I of part D of title XXIII of the Public  
 12       Health Service Act (42 U.S.C. 300cc-40 et seq.) is amend-  
 13       ed by inserting after section 2351 the following:

14       **“SEC. 2351A. MICROBICIDES FOR PREVENTING TRANS-**  
 15               **MISSION OF HIV AND OTHER SEXUALLY**  
 16               **TRANSMITTED DISEASES.**

17       “(a) EXPANSION AND COORDINATION OF ACTIVI-  
 18       TIES.—The Director of the Office of AIDS Research shall  
 19       expand, intensify, and coordinate the activities of the In-  
 20       stitutes with respect to research on the development of  
 21       microbicides to prevent the transmission of HIV and other  
 22       sexually transmitted diseases (in this section referred to  
 23       as ‘microbicide research’).

24       “(b) COORDINATION WITHIN THE NATIONAL INSTI-  
 25       TUTES OF HEALTH.—The Director of the Office of AIDS

1 Research shall coordinate the activities under subsection  
2 (a) among all appropriate institutes and components of  
3 the National Institutes of Health to the extent such insti-  
4 tutes and components have responsibilities that are related  
5 to the development of microbicides.

6 “(c) RESEARCH PLAN.—

7 “(1) IN GENERAL.—The Director of the Office  
8 of AIDS Research, acting in consultation with the  
9 Director of the Institute of Allergy and Infectious  
10 Diseases, shall expedite the implementation of the 5-  
11 year strategic plan for the conduct and support of  
12 research and development of microbicides (in this  
13 section referred to as the ‘Research Plan’), and shall  
14 annually review and as appropriate revise the plan.

15 “(2) REQUIREMENTS.—The Research Plan  
16 shall—

17 “(A) identify current microbicide research  
18 and development activities conducted or sup-  
19 ported by the National Institutes of Health, in-  
20 cluding a description of each current grant and  
21 contract mechanism explicitly designed to facili-  
22 tate microbicide research, including support for  
23 preclinical product development and clinical  
24 trial capacity; and

“(B) describe microbicide research and development opportunities for the five year period beginning three months after the date of the enactment of the Microbicide Development Act of 2001, including professional judgment funding projections, description of objectives with respect to microbicide research, description of the institutes involved and their role in microbicide research, plans for enhancing the capacity of such institutes to carry out the research opportunities, including staffing and resources necessary for carrying out the activities of this section, and discussion of plans for increasing number of investigators in this area of research.

“(3) CONSULTATION.—In developing the Research Plan, the Director of the Office of AIDS Research shall work in close consultation with the Director of the National Institute of Allergy and Infectious Diseases, the Director of the National Institute of Child Health and Human Development, and with all appropriate institutes and components at the National Institutes for Health that have responsibilities that are related to the development of microbicides, with other Federal agencies involved in microbicide

1 research, with the microbicide research community,  
2 and with health advocates.

3 “(4) SUBMISSION OF INITIAL PLAN TO PRESI-  
4 DENT AND CONGRESS.—

5 “(A) IN GENERAL.—The initial Research  
6 Plan shall be developed not later than three  
7 months after the date of the enactment of the  
8 Microbicide Development Act of 2001. The Di-  
9 rector of the Office of AIDS Research shall  
10 transmit such Plan to the Director of NIH, who  
11 shall submit the Plan to the President and the  
12 Congress.

13 “(B) RELATION TO REQUIREMENT OF BI-  
14 ENNIAL NIH REPORT.—Subparagraph (A) shall  
15 be carried out independently of the process of  
16 reporting that is required in section 403.

17 “(d) PROGRAM FOR MICROBICIDE DEVELOPMENT.—

18 “(1) IN GENERAL.—In carrying out subsection  
19 (a), the Director of the National Institute of Allergy  
20 and Infectious Diseases shall establish a program to  
21 support research to develop microbicides that can  
22 substantially reduce transmission of HIV and other  
23 sexually transmitted diseases. In accordance with  
24 scientific opportunities, as such opportunities be-



1       come evident, activities under such program shall  
2       include—

3               “(A) basic research on the initial mecha-  
4               nisms of infection by sexually transmitted  
5               pathogens;

6               “(B) development of appropriate animal  
7               models for evaluating safety and efficacy of  
8               microbicides;

9               “(C) development of formulation and deliv-  
10              ery approaches;

11              “(D) research on targeted designs of  
12              microbicides;

13              “(E) manufacture of candidate products  
14              for testing in animals and humans;

15              “(F) conduct of HIV incidence and  
16              microbicide feasibility studies;

17              “(G) evaluation of microbicides in clinical  
18              trials, both domestically and internationally;  
19              and

20              “(H) behavioral research on use, accept-  
21              ability, and adherence to microbicides.

22              “(2) MICROBICIDE DEDICATED UNIT.—The Di-  
23              rector of the National Institute of Allergy and Infec-  
24              tious Diseases shall organize, within the Prevention  
25              Sciences Branch of the Vaccine and Prevention Re-

1 search Program of the Division of AIDS in the In-  
2 stitute, a dedicated unit charged with carrying out  
3 the program under this subsection. In organizing the  
4 unit, the Director shall designate between three and  
5 five additional full-time employees to the work en-  
6 compassed by the Research Plan, while maintaining  
7 staffing levels in other areas critical to advancing  
8 microbicide research and development.

9 “(e) MICROBICIDE RESEARCH AND DEVELOPMENT  
10 TEAMS.—

11 “(1) IN GENERAL.—The Director of the Na-  
12 tional Institutes of Health shall make awards of  
13 grants or contracts to public and private entities for  
14 the development and operation of not less than four  
15 new multidisciplinary teams to conduct research on  
16 innovative microbicide concepts, including combina-  
17 tion microbicides.

18 “(2) REQUIREMENTS.—Each team assisted  
19 under this subsection shall—

20 “(A) use the facilities of a single institu-  
21 tion, or be formed from a consortium of cooper-  
22 ating institutions, meeting such requirements as  
23 may be prescribed by the Director of the Na-  
24 tional Institutes of Health; and

1           “(B) conduct research on muscosal trans-  
2           mission to design and develop novel  
3           microbicides for the prevention of HIV and  
4           STD infection, including research into HIV and  
5           STD pathogenesis, reproductive tract biology  
6           and toxicology, concept testing in animal mod-  
7           els, and formulation and delivery design.

8           “(f) REPORT TO CONGRESS.—Not later than one  
9           year after the date of the initial submission of the Re-  
10          search Plan under subsection (c)(1), and annually there-  
11          after, the Director of the Office of AIDS Research, in con-  
12          sultation with the Director of the Institute of Allergy and  
13          Infectious Diseases, shall submit to the Committee on En-  
14          ergy and Commerce and the Committee on Appropriations  
15          of the House of Representatives and the Committee on  
16          Health, Education, Labor, and Pensions and the Com-  
17          mittee on Appropriations of the Senate a report that de-  
18          scribes the activities of the National Institutes of Health  
19          regarding microbicide research. Each such report shall  
20          include—

21               “(1) an updated Research Plan, including pro-  
22          fessional judgment funding projections;

23               “(2) an assessment of the implementation of  
24          such plan;

1           “(3) a description and evaluation of the  
2           progress made, during the period for which such re-  
3           port is prepared, in the research on microbicides;

4           “(4) a summary and analysis of expenditures  
5           made, during the period for which the report is  
6           made, for activities with respect to microbicides re-  
7           search conducted and supported by the National In-  
8           stitutes of Health, including the number of full-time  
9           equivalent employees; and

10          “(5) such comments and recommendations as  
11          the Director of the Office of AIDS Research con-  
12          siders appropriate.

13          “(g) COORDINATION WITH OTHER FEDERAL AGEN-  
14          CIES.—The Director of the Office of AIDS Research shall  
15          consult with the Director for the Centers for Disease Con-  
16          trol and Prevention and the United States Agency for  
17          International Development in developing the Research  
18          Plan that takes into consideration research on HIV and  
19          other sexually transmitted diseases and microbicides car-  
20          ried out at the Centers for Disease Control and Prevention  
21          and the United States Agency for International Develop-  
22          ment.

23          “(h) DEFINITION.—For purposes of this section, the  
24          term ‘HIV’ means the human immunodeficiency virus.  
25          Such term includes acquired immune deficiency syndrome.

1       “(i) AUTHORIZATION OF APPROPRIATIONS.—For the  
 2 purposes of carrying out this section, there are authorized  
 3 to be appropriated such sums as may be necessary for  
 4 each of the fiscal years 2002 through 2004.”.

5       **TITLE     II—MICROBICIDE     RE-**  
 6       **SEARCH   AT   THE   CENTERS**  
 7       **FOR   DISEASE   CONTROL   AND**  
 8       **PREVENTION**

9       **SEC. 201. MICROBICIDES FOR PREVENTING TRANSMISSION**  
 10               **OF HIV AND OTHER SEXUALLY TRANSMITTED**  
 11               **DISEASES.**

12       Part B of title III of the Public Health Service Act  
 13 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
 14 tion 317P the following:

15       **“SEC. 317Q. MICROBICIDES FOR PREVENTING TRANS-**  
 16               **MISSION OF HIV AND OTHER SEXUALLY**  
 17               **TRANSMITTED DISEASES.**

18       “(a) EXPANSION AND COORDINATION OF  
 19 MICROBICIDE RESEARCH ACTIVITIES.—The Secretary,  
 20 acting through the Director of the Centers for Disease  
 21 Control and Prevention, shall expand, intensify, and co-  
 22 ordinate the activities of such Centers with respect to re-  
 23 search on microbicides to prevent the transmission of HIV  
 24 and other sexually transmitted diseases.

1       “(b) GRANTS REGARDING MICROBICIDE RE-  
2 SEARCH.—In order to contribute to the rapid evaluation  
3 of safe and effective microbicides for the prevention of  
4 HIV and other sexually transmitted diseases, the Sec-  
5 retary may in carrying out subsection (a) make grants to  
6 public and nonprofit private entities for the purpose of—

7               “(1) laboratory research in preparation for, and  
8 support of, clinical microbicide trials;

9               “(2) conducting behavioral research in prepara-  
10 tion for, and support of, clinical microbicide trials;

11               “(3) developing and characterizing domestic  
12 populations and international cohorts appropriate  
13 for Phase I, II, and III clinical trials of candidate  
14 topical microbicides;

15               “(4) conducting Phase I and II clinical trials to  
16 assess the safety and acceptability of candidate  
17 microbicides;

18               “(5) conducting Phase III clinical trials to as-  
19 sess the efficacy of candidate microbicides;

20               “(6) providing technical assistance to, and con-  
21 sulting with, a wide variety of domestic and inter-  
22 national entities involved in developing and evalu-  
23 ating topical microbicides, including health agencies,  
24 extramural researchers, industry, health advocates,  
25 and non-profit organizations; and

1           “(7) developing and evaluating the diffusion  
2           and effects of implementation strategies for use of  
3           effective topical microbicides.

4           “(c) SELECTION OF AGENTS AND TRIAL DESIGNS;  
5 COORDINATION WITH OTHER AGENCIES.—In coordina-  
6 tion and collaboration with the Director of the National  
7 Institutes of Health and the Administrator of the United  
8 States Agency for International Development, the Sec-  
9 retary shall select agents and trial designs, develop clinical  
10 trial capacity as described in subsection (b), share experi-  
11 ence, and avoid duplication of effort.

12          “(d) ANNUAL REPORTS.—Not later than three  
13 months after the date of the enactment of the Microbicide  
14 Development Act of 2001, and annually thereafter, the  
15 Secretary shall submit to the Energy and Commerce Com-  
16 mittee of the House of Representatives and the Health,  
17 Education, Labor, and Pensions Committee of the Senate  
18 a report on the activities carried out under this section  
19 by the Secretary. Each such report shall include—

20           “(1) a description of research with respect to  
21           microbicide research and development;

22           “(2) a description and evaluation of the  
23           progress made, during the period for which such re-  
24           port is prepared, in the research on microbicides;  
25           and

1           “(3) a summary and analysis of expenditures  
2       made, during the period for which the report is  
3       made, for activities with respect to microbicides con-  
4       ducted and supported by the Centers for Disease  
5       Control and Prevention.

6       “(e) DEFINITION.—For the purposes of this section,  
7       the term ‘HIV’ means the human immunodeficiency virus.  
8       Such term includes acquired immune deficiency syndrome.  
9       “(f) AUTHORIZATION OF APPROPRIATIONS.—For the  
10      purposes of carrying out this section, there are authorized  
11      to be appropriated such sums as may be necessary for  
12      each of the fiscal years 2002 through 2004.”.

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